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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/737,190	12/14/2000	Tetsuo Shibuya	14043 (JP919990270US1)	9159

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SCULLY, SCOTT, MURPHY & PRESSER  
400 Garden City Plaza  
Garden City, NY 11530

EXAMINER
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LY, CHEYNE D

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

317

## Office Action Summary

Application No.

09/737,190

Applicant(s)

SHIBUYA, TETSUO

Examiner

Cheyne D Ly

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 3-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. <u>12/03</u>   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 23, 2003 has been entered.

2. Claims 2 and 12 are examined on the merits.

### **CLAIM REJECTIONS - 35 USC § 112**

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. This rejection is maintained with respect to claims 2 and 12, as recited in the previous Office Action, mailed August 26, 2003.

6. Claim 2, line 1, and claim 12, line 1, the preamble recites a method for analyzing the structure of a target array while the body of the claim recites steps for changing a variable that is included in a target array. Claims 2 and 12 are vague and indefinite because it is unclear whether the target array, which is embodied in this method claim, is an apparatus such as a microarray, a data structure or the data representing the elements of the array apparatus. Clarification of the metes and bounds is required.

### **RESPONSE TO ARGUEMENTS**

7. Applicant's argument via amendment to claims 2 and 12 has been acknowledged and found to be unpersuasive because the said amendment does not help Applicant overcome the vague and indefinite issue of claims 2 and 12 as discussed below. Further, Applicant argues that an "array" is a term of art in the computer science that represents a set of elements in an ordered sequence. However, the instant invention is directed to analyzing the structure of mRNA or DNA sequence as directed to the field of biotechnology. It is well documented that the terms array and microarray have been used interchangeably to refer to set elements in an ordered sequence in the biotechnology art.

#### **NEW 35 USC § 112 SECOND PARAGRAPH REJECTION**

8. Specific to claim 2, steps (a) and (b), sub-steps (i), (ii); and claim 12, steps (a) and (b), the phrase replacing in the first/second array a corresponding first occurrence of each variable in the target array causes the claims to be vague and indefinite because it is unclear whether the variable is replacing the first or second array or the variable is to replace elements within the respective arrays. Clarification of the metes and bounds is required.

9. Specific to claim 2, steps (a) and (b), sub-steps (i) and (ii), the phrase "replacing...into information" causes the claim to be vague and indefinite because it is unclear an array is being converted into information or the content of said array is replaced with information.

Clarification of the metes and bounds is required.

#### **CLAIM REJECTIONS - 35 USC § 102**

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 2 and 12 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kadashevich et al. (US005369577A).

12. This prior art rejection is directed to an array apparatus comprising data elements as discussed in the above 35 USC §112, Second Paragraph, rejection.

13. Kadashevich et al. discloses a method of making and using a morphological (structure) analyzer of a first and second set of words (array of different elements) (column 2, lines 12 to column 3, line 21). The text is organized within an array (column 8, lines 19-31), as in instant claim 2, steps (a) and (b).

14. The analyzer parses the text and traverses said text to identify matching letters (complement) for each character in the input word (first array) against a sequence (second array). The analyzer traverses the lexicon tree (predetermined direction), checking all possible interpretations of each character in the input string. If the end of the input string is reached (location) at the same point that the end of a stem or suffix is reached, then the input word has been successfully parsed (column 23, line 53 to column 24, line 4; and column 25, Traversing the Lexicon §), as in instant claim 2, steps (a) and (b), (i).

15. In the event of words that are not valid, the words must be replaced by either the contents of <BAS> fields or by a word formed by combining the abstract stem with a root suffix, as in instant claim 2, steps (a) and (b), (ii).

16. The performance of the traversing the lexicon step is a recursive function (repeat) (column 25, lines 35-49), as in instant claim 2, steps (a) and (b), (iii).

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17. The method of Kadashevich et al. comprises steps for analyzing a structure of an array as directed to the current word (first array) and another word (second array) (column 8, lines 27-49), as instant claims 2 and 12, step (c).

18. The analyzer comprises a derivational history including information about any parses that were successfully performed by the recognition engine on the input word. The derivational history contains, for each successful parse of the input word, the part of speech of the input word for that particular parse (prior occurrence) (column 2, lines 20-25), as in instant claim 12, steps a) and b).

### **CLAIM REJECTIONS - 35 USC § 103**

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 2 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Jensen et al. (April 2000) taken with Eisen (1999).

21. This rejection is maintained with respect to claims 2 and 12, as recited in the previous Office Action, mailed August 26, 2003.

22. Applicant presents argument by amendment to claims 2 and 12, which has been fully considered and found to be unpersuasive due to the new 35 USC §112, Second Paragraph, issue raised by the new limitations of manipulating the first and second array. Therefore, the new limitations of manipulating the first and second array do not help Applicant overcome the instant prior rejection.

23. Specific to Applicant's argument that the method of Jensen et al. "fails to teach or suggest the step of traversing the target array as in claims 2 and 12, Applicant's argument has been fully considered and found to be unpersuasive. Consistent with Applicant's definition of an array (Remarks, November 26, 2003, page 8, lines 20-23), Jensen et al. discloses a plurality of arrays as directed to DNA in Table 1 and arrays are traversed in an iterative fashion (two sweeps) (page 328, column 1, lines 30-38).

24. Specific to Eisen, Applicant argues the disclosure of Eisen has no relevance to the method cited in claims 2 and 12 due to said disclosure being directed to DNA microarray. Applicant's argument has been fully considered and found to be unpersuasive due to the scope of claims 2 and 12 includes DNA microarray. Further, claims 2 and 12 are vague and indefinite in regard to the limitation of array as discussed above.

25. It is re-iterated that Jensen et al. discloses a method for functional annotation associated with each gene or ORF was converted into a pseudo-sequence by removal of all non-alphanumeric characters...For each of the approximately 10 000 words in the dictionary, the set of 500 bp upstream regions was divided into a corresponding positive set consisting of the sequences containing the word in their functional annotation and negative set not containing the word (Page 327, column 2, lines 30-37 to Page 328, column 1, lines 1-3). "The two strands are treated separately when counting patterns. By doing so we gain sensitivity on patterns that show strong preference for one orientation" (Page 327, column 1, lines 43-47). "In the first sweep, the number of sequences containing each pattern is stored in one counter. During the second sweep, the number of these sequences yet encountered and the highest value of  $|N_{x1} - n_i|$  so are stored

in two other counters” (Page 328, column 1, lines 33-37). Table 3 (Page 330) discloses the converted data from three microarray experiments and the array data is analyzed respective of each other, as in instant claims 2 and 12.

26. However, Jensen et al. does not specify a method for analyzing the structure of an array.

27. Eisen discloses a method for analyzing the structure a DNA array and the location of each DNA target contain within an array via a GRIDDING process (page 4, lines 9-31). After “gridding” the first array from a batch, it is generally possible to use this initial grid for all subsequent arrays in the batch (page 20, lines 6-9), as in claims 2 and 12.

28. It is noted that Jensen et al. discloses a general method for analyzing large amount of data generated from DNA arrays (abstract etc.), thus, suggests that the method of Jensen could be applied to any DNA array data of which Eisen is a specific array analysis that is therefore suggested within the generic Jensen et al. description.

29. Eisen discloses a method for analyzing the structure and the location of each DNA target contain within an array via a GRIDDING process (page 4, lines 9-31). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the method of analyzing the structure of a DNA array as taught by Jensen et al. and Eisen.

### **CONCLUSION**

30. NO CLAIM IS ALLOWED.

31. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the



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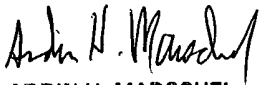
Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

34. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

C. Dune Ly  
3/2/04

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER